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10/535,446

10/31/2006

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03/13/2009

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/535,446 | <b>Applicant(s)</b><br>KADYK ET AL. |  |
|                              | <b>Examiner</b><br>SHERIDAN SWOPE    | <b>Art Unit</b><br>1652             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1-24 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-12 and 16-19, drawn to a method for identifying a RAC pathway modulator.

Group II, Claims 13-15, drawn to a method for modulating a RAC pathway using a RAC defective cell.

Group III, Claims 20-22, drawn to a method for modulating a RAC pathway using a RAC+ mammalian cell.

Group IV, Claims 23-25, drawn to a method of diagnosis using a modifier of RAC (MRAC) expression assay.

For each of Inventions I-VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-IV and one or more of Inventions (A)-(FF), as indicated.

If Group I is elected, elect one of:

- (A) A protein assay
- (B) A nucleic acid assay

If Group I is elected, elect one of:

- (C) In vivo
- (D) In cell culture
- (E) In vitro

If Group I is elected, elect one of:

- (F) Using a RAC defective cell
- (G) Using a RAC+ cell

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If Group I is elected, elect one of:

- (H) Apoptosis
- (I) Cell proliferation
- (J) Angiogenesis
- (K) Hypoxia
- (L) Binding assay with MRAC
- (M) Nucleic acid expression

If Group I is elected, elect one of:

- (N) Not additionally testing in a RAC defective model system
- (O) Additionally testing in a RAC defective model system

If Group I is elected, elect one of:

- (P) Not Additionally testing in a MRAC+ system
- (Q) Additionally testing in a MRAC+ system

If (Q) is elected, elect one from:

- (i) In vivo
- (ii) In cell culture

If Group II is elected, elect one of:

- (R) In vivo
- (S) In cell culture

If Group II is elected, elect one of:

- (T) Not additionally testing in a CSNK+ model system
- (U) Additionally testing in a CSNK+ system

If (U) is elected, elect one of:

- (i) In cell culture
- (ii) In vivo

If (ii) is elected, elect one of:

- (a) The animal is RAC pathway defective
- (b) The animal is not RAC pathway defective

If (U) is elected, elect one of:

- (i) A RAC pathway defective animal
- (ii) Not a RAC pathway defective animal

If Group III is elected, elect one of:

- (V) Binds MRAC protein
- (W) Binds MRAC nucleic acid

If Group III is elected, elect one of:

- (X) The animal is RAC pathway defective
- (Y) The animal is not RAC pathway defective

If Group III is elected, elect one of:

- (Z) Small molecular modulator
- (AA) A nucleic acid
- (BB) An antibody

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If Group IV is elected, elect one of:

(CC) Protein expression

(DD) Nucleic acid expression

If Group IV is elected, elect one of:

(EE) Cancer

(FF) A disease other than cancer

The inventions listed as Groups I-IV(A)-(FF) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-IV(A)-(FF) appears to be that they all relate to MRACs. However, MRACs were well known in the art. Moreover, Wong et al, 2000 (Fig 6) teach modulating a cell with a MRAC modulator, which anticipates Claim 20. Therefore Groups I-IV(A)-(FF) share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the methods of Groups I-IV(A)-(FF) do not use the same reagents or produce the same results. Accordingly, Groups I-IV(A)-(FF) are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention and sub-invention(s) to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be

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considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should Applicants traverse on the ground that the inventions are linked by a special technical feature, Applicants should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652